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Do theatre staff use face masks in accordance with the manufacturers' guidelines of use?

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Abstract

Aim: Surgical face masks are worn by theatre staff to protect the surgical site from airborne contamination and the wearer from bodily fluid splash. This observational/audit aimed to assess whether theatre staff wear masks in accordance with manufacturers'/Centers for Disease Control and Prevention (CDC) guidelines of use.

Methods: A total of 1034 surgically scrubbed staff were assessed on their technique of applying surgical face masks, compared to the CDC guidelines as manufacturers' guidelines were not available as per Health and Safety Executive guidelines.

Results: Only 18% of surgically scrubbed staff fully complied with the CDC guidelines on the application of a face mask. Compliance was worst in urology, ophthalmology and vascular surgeons, whereas orthopaedic and plastic surgeons were the most compliant.

Discussion: Compliance with CDC face mask guidelines may have an impact on surgical site infections (SSI) and protection of staff from body fluid splash, but most staff do not comply with these guidelines.

Conclusions: Most operating theatre staff do not apply a face mask using correct technique, outlined in CDC guidance, which may increase SSI rates. Staff are not aware of existing guidelines for donning a mask.

Keywords

Face mask, surgical, theatre, guidelines

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Introduction

Surgical face masks are worn in the perioperative period for two reasons: to protect the patient and also the wearer. Protecting the patient is of paramount importance, with surgical site infections (SSI) increasing the length of hospital stay by an average of 6.5 days (Plowman, 2000) resulting in costs to the NHS in England of an estimated £1 billion (Vincent and Edwards, 2016). SSIs have been shown to significantly increase mortality as well as morbidity (Coello et al., 2005). Second, appropriate face mask application provides protection for theatre staff themselves, given that blood or body fluid splash is present in up to 45% of operations (Davies et al., 2007) and that there is risk of disease transmission; in the case of HIV, there is a 0.1% risk of transmission with mucus membrane exposure to HIV-infected blood (Saltzman et al., 2005).

National guidance in the UK (National Institute of Health and Clinical Excellence [NICE], 2008) outlines in '*Best practice in theatre wear*' that:

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> 'Staff should wear specific non-sterile theatre wear (scrub suits, masks, hats and overshoes) in all areas where operations are undertaken' (NICE guidance CG74 [2008], p. 29).

The guidance acknowledges that there is no research evidence for this recommendation with regards to face mask wearing, citing that wearing masks is important in maintaining theatre 'discipline' and may thereby contribute to minimising the risk of SSI. There is some indirect evidence that theatre discipline is linked to SSI rates; one paper found a noisy theatre environment was associated with an increased rate of SSI (Kurmann et al., 2011).

This paper critically appraises the literature investigating the proper application of face masks and whether it subsequently reduces risk to patient and surgical staff, then importantly presents a large primary dataset investigating whether face masks are worn appropriately, in line with CDC guidance.

Background

Surgical face masks have been used for over a century, prompted by the findings that there were bacteria present in droplets expelled from the nose and mouth (Flugge, 1897). The landmark trial for the efficacy of face masks followed when an unusual outbreak of haemolytic streptococcus SSI occurred after clean surgical cases in one hospital in 1926 (Meleney, 1926). The infection was assumed to be a consequence of airborne contamination from the operating staff, after it was found that one-third of them were colonised with the same rare strain of streptococcus as that found in the SSI. None of the operating staff were wearing face masks (Meleney, 1926). This prompted strict masking of the staff and a follow-up trial. The findings demonstrated that despite staff remaining colonised with the streptococcus strain, the incidence of SSI significantly reduced (Meleney, 1927). Initially, uptake of face mask wearing was low, unsurprisingly perhaps due to the fact that the original masks were very uncomfortable and of questionable efficacy, particularly as they became moist with secretions from the wearer.

Surgical face masks evolved from the gauze-like material and are made from at least three layers of non-woven fabric with two filters. In vitro, the filters of modern face masks have shown to considerably outperform old-style fabric face masks, specifically in relation to submicrometre-sized aerosols to which the wearer might be exposed, when air/aerosol flow is directed through the face mask filters (Chen and Willeke, 1992).

Face mask design continues evolving with regards to comfort and direct filtering capability through the material, with British Standards Institution adopting EU guidelines on quantifying mask performance. However, they do not make public a comparative roster of mask performances currently or compared to historic masks (British Standards Publication, 2014).

It is also unclear how long modern face mask material is effective for. One manufacturer is quoted in the most recent Cochrane review (Vincent and Edwards, 2016) that protection is for at least 4 h (University Hospital Supplies [UHS], 2000), but of course this would rely on many interacting factors: the size of the microbe-containing droplets; wearer minute ventilation; and moisture content of the expired air. Indeed, another study, comparing the old-style fabric and more modern two-ply masks, found no significant difference between the two types of mask in preventing bacterial dispersal when worn, and that after 2 h, neither mask was effective at reducing the dispersed bacterial count when theatre staff exhaled through their masks onto a blood agar plate (Kelkar et al., 2013), highlighting another important issue: that of fit on mask performance.

There are numerous potential ways in which the suboptimal application of face masks can reduce efficacy and potentially contribute to contamination of surgical wounds. There are, however, no sizeable datasets on compliance with the CDC guidelines that outline how to optimally apply a face mask (Table 1), an issue that this paper aims to address (Communicable Disease Control and Prevention, 2017).

Perhaps the most important problem is face mask 'venting'. This problem likely occurs most markedly when the mask is incorrectly moulded to the nose and/or the drawstrings are not fastened sufficiently, allowing air and aerosols to pass out of the mask between the mask and nose, along the wearer's cheek, or out of the bottom of the mask, as shown by Tang et al. (2009) who took schlieren optical images of air flow when individuals used surgical face masks. The CDC guidance states that the stiff edge of the face mask should be pinched or moulded to the nose to achieve effective fit (Table 1) in order to prevent this, but for better fit the additional criteria of two-handed moulding was audited, to improve fit to the nose and cheek as suggested by the National Institutes of Health (NIH), possibly reducing venting (NIH, 2011).

Capillary action along the threads and through the mask ('wicking') has been identified as a contributing factor to infection, by helping transport the aerosols containing the bacterium out of the face mask and potentially into the surgical site (Belkin, 1996). Additionally, a 'wiggling' motion of the mask against the face and hair, rubbing off particulate matter that might fall into the surgical site, has been proposed to increase the risk of SSI with face mask wearing, though, clearly this will have little effect for the staff in theatres who do not stand over the surgical site (Schweizer, 1976), and this is further pronounced in those who are not clean-shaven (McLure et al., 2000); for this reason, despite not being part of the CDC criteria, being clean-shaven was included in the additional audited criteria (for men only) (Table 2).

Likely secondary to these issues with fit, modern evidence for face mask efficacy in vitro is lacking. A 2016 Cochrane literature review (Vincent and Edwards, 2016) compared the rates of SSI in clean surgery when members

Table 1. CDC guidelines describing how to put on and remove a face mask.

1	Clean your hands with soap and water, or hand sanitiser before touching the mask.
2	Remove a mask from the box and make sure there are no obvious tears or holes in either side of the mask.
3	Determine which side of the mask is the top. The side of the mask that has a stiff bendable edge is the top and is meant to mould to the shape of your nose.
4	Determine which side of the mask is the front. The coloured side of the mask is usually the front and should face away from you, while the white side touches your face.
5	Follow the instructions below for the type of mask you are using. *-Face mask with **ear loops**: Hold the mask by the ear loops. Place a loop around each ear.* *-Face mask with **ties**: Bring the mask to your nose level and place the ties over the crown of your head and secure with a bow.* *-Face mask with **bands**: Hold the mask in your hand with the nosepiece or top of the mask at fingertips, allowing the headbands to hang freely below hands. Bring the mask to your nose level and pull the top strap over your head so that it rests over the crown of your head. Pull the bottom strap over your head so that it rests at the nape of your neck.*
6	Mould or pinch the stiff edge to the shape of your nose.
7	If using a face mask with ties: Take the bottom ties, one in each hand, and secure with a bow at the nape of your neck.
8	Pull the bottom of the mask over your mouth and chin.

CDC Guidelines for donning a face mask.

Table 2. Showing compliance to different criteria.

	Failed to meet criteria n=1034	Met criteria n=1034	Compliance (%)
CDC compliance	844	190	18
Nose and mouth covered	900	134	13
Extended criteria met	875	159	15.3
Visor use	997	37	3.6

of the surgical team were, or were not, wearing face masks. Data were taken from three randomised controlled trials (RCT) or quasi-RCTs involving 2113 participants and found no statistically significant difference in SSI rates between the masked and unmasked groups. These results need to be interpreted with caution. Importantly, none of the included RCTs took any steps to monitor how the surgical face masks were worn, a point that is the main focus of this paper. Furthermore, one of the three studies only included non-scrubbed staff in the operating theatre (i.e. those operating likely still wore face masks) and the other two studies sampled all members of the theatre team; of course, the majority of these are distant from the operating site, so will have a negligible potential infection effect compared to a surgeon operating at the surgical site. Furthermore, the meta-analysis excluded data obtained from operations involving implantation of prostheses, which was aimed at protecting the integrity of the data, as such operations have a greater SSI risk; however, it does limit the applicability of the dataset. The authors of the meta-analysis postulated that the main reason that face mask wearing is not effective in vivo is due to airflow around the sides of the mask.

In terms of the mask affording protection to the healthcare professional, the average risk across all types of surgery for splash has been established as around 45% (Davies et al., 2007). Importantly, no type of surgery sampled had zero risk of splash from this study and, perhaps surprisingly, laparoscopic surgery had a higher risk of splash, principally when the pneomoperitineum is decompressed (Davies et al., 2007). The risk for HIV from mucous membrane exposure is well documented (Saltzman et al., 2005) but there have also been incidences of Hepatitis C (Ippolito et al., 1998), Cytomegalovirus and Hepatitis B transmission to healthcare professionals via mucous membrane exposure.

To summarise, apart from a paired case-series a century ago, the literature does not currently provide robust evidence that mask wearing in the operating theatre reduces SSI but does provide evidence that many factors related to improper application reduce face mask performance. We hypothesise that face masks are not worn properly by

surgically scrubbed theatre staff and postulate that this may be the reason why face masks have been found to be ineffective at preventing SSI in the recent past.

Methods

Experimental protocol and data collection

Data were collected over a four-week period from nine large, high-performing (as defined by the Department of Health) NHS hospitals in the UK. This was done as an observational study/audit.

The masks used included the Kimberly-Clark® Fog-Free Surgical Mask, Fluid shield with wrap around splash-guard and Kimberly-Clark® Technol The Lite One® Surgical Mask, Shermond Uniprotect® Surgical Face Masks and Fluid Protect® Surgical Face Mask and Anti-Fog Visor.

Staff were observed applying the surgical masks and marked against a preformed checklist (see Appendix 1) with the result being recorded. Staff were verbally consented and informed that researchers were auditing scrubbing procedures and observed throughout the entire scrubbing process, thus being partially blinded to the specific data being collected, i.e. that mask fitting was the focus of the data collection, in an attempt to reduce performance bias. The data collectors were all surgical doctors of various grades including consultant, who followed a preformed checklist. Each had teaching on mask application before data collection to ensure uniformity. They had assessed application of the preformed checklist and deemed to be equivocal by the lead author.

Participants

The inclusion criteria encompassed operating theatre staff members that were surgically scrubbed during an operation or procedure including, but not limited to, surgeons, assistants, scrub nurses, Operating Department Practitioner (ODPs), anaesthetists and medical students. There were no exclusion criteria as to the procedure being performed.

Staff names were collected to avoid repetition of data collection but were not linked to the variable data of the study; these records were destroyed after the collection process.

Guidelines for application

Guidelines for applying the masks follow CDC recommendations that are outlined in Table 1. As mentioned in the introduction, two further criteria were added to the audit tool: whether two hands were used to mould the face mask to the shape of the nose; and whether the theatre staff were clean-shaven. CDC guidelines are used in the absence of manufacturers guidelines as per the Health and Safety Executive (HSE) guidelines (2008).

Results and power calculation

G-Power priori analysis was used to assess an appropriate power. A 3% margin of error, 95% confidence level and a suspected response distribute being $\geqslant$ 70% with a P value of 0.5, calculated a required sample size of 1034.

Ethical considerations

There are no ethical issues to address in this observational study/audit; therefore, no ethical approval was required.

Results

A total of 1034 surgically scrubbed theatre personnel were examined for how they applied a face mask: 18% (n = 190) complied with the CDC guidance on proper application of a face mask (see Table 2). When additional measures were applied to the CDC criteria as this paper suggests—of being clean-shaven and using two hands to mould the mask to the face—the compliance rate dropped further, to 15% (n = 159).

Of the 1034 healthcare professionals surgically scrubbed, 902 (87%) covered both the nose and mouth with the face mask. Covering the eyes with a visor was rarely performed (4%).

When splitting the data down by specialty, the heterogeneity in data spread was marked. Orthopaedics had the highest compliance with CDC guidance (73%). Plastic surgery had the second best with 45%, with worst compliance in urology, ophthalmology and vascular surgery with 0% full compliance with the CDC guidance (full results below on Figure 1).

In terms of compliance by profession/training grade, the junior doctors (foundation doctors and core trainees) had the highest compliance with CDC guidance, of approximately 50%, with consultants, nurses and anaesthetists having the lowest levels of compliance, each $<$ 10% (the full results can be viewed in Figure 2 below). This, however, could be skewed due to anaesthetists performing procedures scrubbed with much smaller incisions, or even just needle insertion, such as spinal or epidural anaesthesia, where omitting a face mask might be deemed less hazardous.

Discussion

This study, investigating the compliance of surgically scrubbed staff wearing face masks in accordance with CDC guidance (2017), demonstrated that less one-fifth of surgically scrubbed theatre staff comply. There are likely many reasons for this low compliance, which will be discussed below.

The low compliance may actually yet be an overestimation too, as one of the limitations of this study was that staff could not be completely blinded to the fact they were being assessed (though they were not told about which part of the

Figure 1. Showing compliance by specialty.

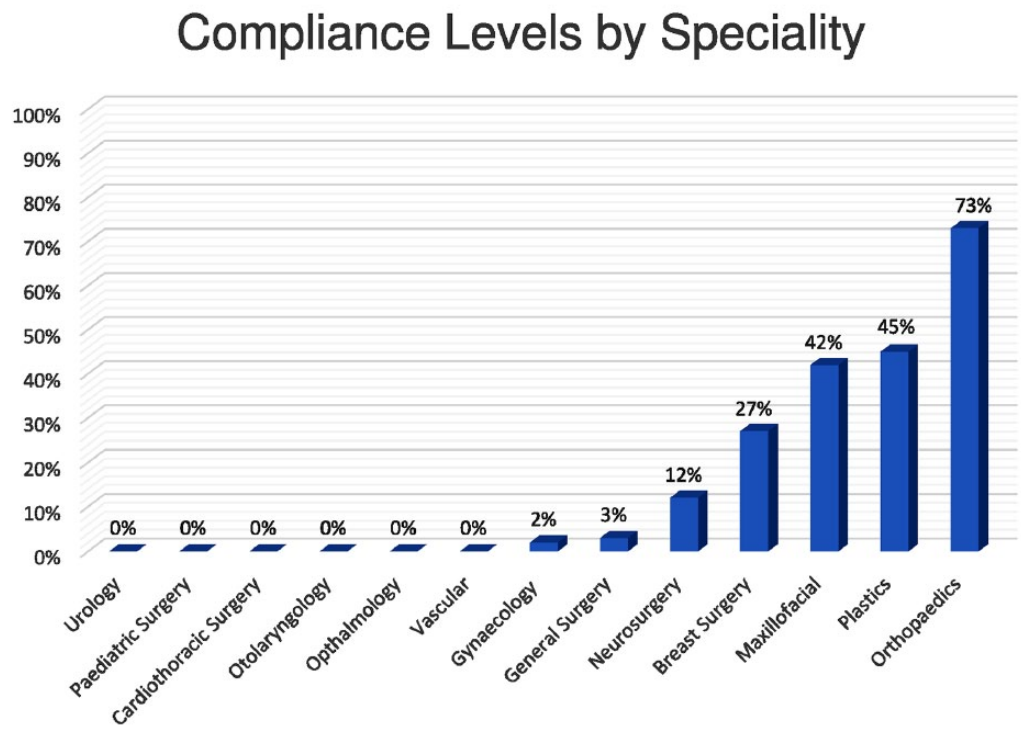
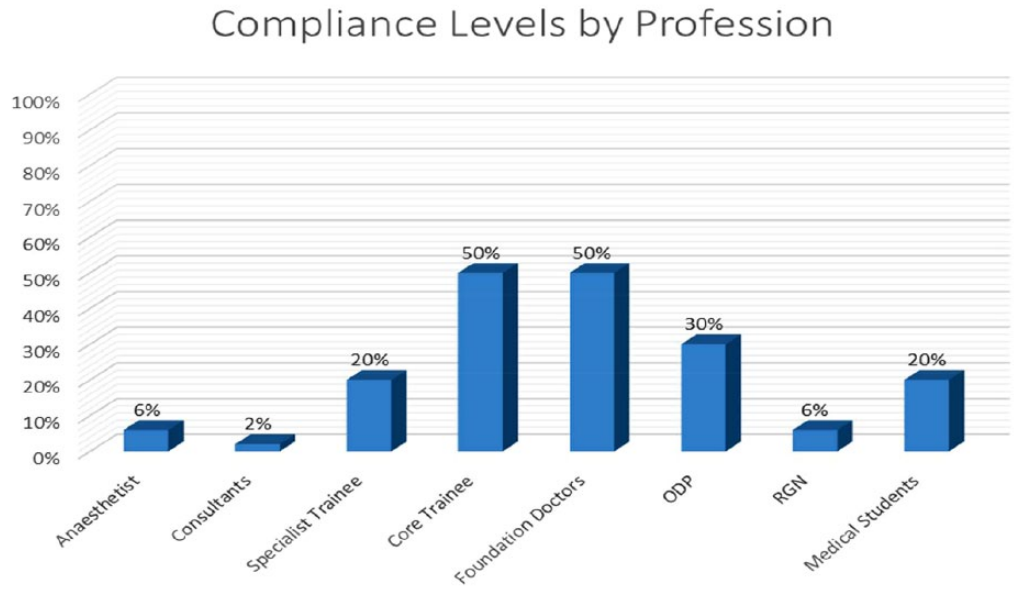


Figure 2. Showing compliance by profession.



scrubbing regimen was being audited). They may have altered their practice on account of this.

Some surgically scrubbed staff may not wear masks on account of the lack of robust evidence that they reduce the

incidence of SSI. As discussed in the introduction, in the only meta-analysis of surgical face mask effect on SSI, there was no evidence that mask wearing reduced the rate of SSI in clean operations (Vincent and Edwards, 2016). This large primary dataset has highlighted that face masks are not being worn properly by surgically scrubbed staff; therefore, we postulate that the aforementioned meta-analysis may underestimate the potential of masks to prevent SSI. This is coupled with our prior stated reservations on the results of the meta-analysis; as all members (not just surgically scrubbed) of staff were included in that analysis – many whom would be distant from the surgical site.

It is clear from the results that there was marked heterogeneity in how face masks are applied between the specialties and this illustrates another reason why some surgically scrubbed staff may not be applying face masks correctly. Those who operate on non-clean sites may deem their aerosolised breath insignificant, particularly in comparison to the dirty contaminants they will encounter in the operation, e.g. on certain sites such as the gastrointestinal tract. Orthopaedic and plastic surgery had the highest compliance (73% and 45%, respectively); this is perhaps unsurprising in the fact that SSI might be of the highest consequence in these specialties, with the implantation of prostheses in orthopaedics and infections in bone and deep tissues being of particularly high consequence causing residual and hard to treat infection, and in plastic surgery the high consequence of a graft infection making it often quickly unviable. Specialties in which operations are not deemed clean, as defined in Mangram (1999) as 'an uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital or uninfected urinary tract is not entered', such as general surgery, may have deemed there to be less contribution of wearing a mask to rates of SSI in their operating environment, due to the contaminated bodily cavities they enter as a matter of course in many of their repertoire of operations.

Other reasons to explain the low compliance with correctly applying a surgical face mask may be that surgically scrubbed staff find the masks uncomfortable if fitted properly to the face, may not read the manufacturers', or CDC, guidance on how to apply them due to time limitations or the lack visible instructions or awareness, or simply not properly fit them as part of a lack of theatre discipline.

Given the fact that 'venting' and 'wiggling' are thought to reduce the efficacy of the surgical face mask, extra audited criteria were added to the CDC guidance: being clean-shaven and using two hands to mould the mask to the face. Compliance with these extra guidelines was similar to the CDC guidance compliance (15% vs. 18%). It would be difficult to assess any real-life clinical outcome difference if these guidelines were to be added, but they perhaps might be considered in higher-risk surgeries to reduce the risk of venting, and debris being generated by the 'wiggling' action. The NHS is, however, a wide and diverse organisation that encompasses many cultures and religions, for some of which shaving is not acceptable – and though in many institutions hoods are mandated in some forms of surgery for those with beards, there is conflicting evidence as to whether a hood and face mask actually reduces the risk of SSI when compared to a face mask alone (McLure et al., 2000; Parry et al., 2016).

With regards to the protection of operating staff at risk of splash, the HSE guidance is clear in the message when there is a risk of exposure to blood or blood borne viruses: '…protect the eyes and mouth by means of a visor or goggle/safety spectacles and a mask when splashing is a possibility…' (HSE, 2008). Given the data available (Davies et al., 2007), it is difficult to argue that there are not many surgeries in which there is no risk of splash, so it is perhaps surprising that only 4% of healthcare professionals wore visors. It was noted that some surgically scrubbed theatre staff wore glasses, but this was not included in the audit tool as glasses are not considered to provide adequate eye protection, as they do not afford protection at the sides of the face.

With regards to both patient and staff protection, NICE evidence review makes the pertinent point that though the evidence for face mask wearing in the operating theatre might not be strong, being part of hygiene discipline that is adopted as a policy by staff and taken seriously is perhaps important in itself.

Future research regarding surgical face mask usage should be clearly separated dependent on the operating theatre staff it relates to: those who are surgically scrubbed or those who are in general theatre clothing (i.e. not directly involved in the procedure/operation occurring). The Cochrane review provides equivocal evidence on the impact of wearing a face mask for general staff in theatres and this cannot be generically applied to surgically scrubbed staff who are in close proximity to the operating site. Nevertheless, it would not be ethical to randomise surgically scrubbed staff members to wear or omit face masks, as it is likely the incidence of SSI would be unacceptable, though this is based on logic and evidence from the early 20th century. This paper has highlighted the fact that face masks are frequently not worn properly; we have putatively suggested further criteria for possible inclusion in future guidance, based on our review of the literature. Furthermore, the low numbers of surgically scrubbed staff wearing visors to cover their eyes and rest of their face has been noted, despite the HSE guidance; perhaps hospitals should encourage this and ensure these types of face masks are available to surgically scrubbed theatre staff. There also needs to be more education to staff on how to wear a surgical face mask as this currently does not exist and there is a failure to provide signposts to the correct guidelines.

Conclusion

In conclusion, most surgically scrubbed theatre staff do not comply completely with CDC guidance on face mask application, nor the HSE guidance on protection from surgical splash, and we cautiously hypothesise that this might have an effect on both the rate of SSI and the chance of operating staff acquiring infections from the operative site. We believe that the implications of this research are that surgically scrubbed staff should be made aware of the importance of proper fitting of a face mask to optimise efficacy, as well as being provided with the appropriate eye protection so as to reduce potential infection risk from surgical splash, as stated in HSE guidance. Failure to follow HSE guidance is unlawful.

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Appendix 1

Table showing the data collection points.

Clean-shaven	Wash hands at beginning	Inspect mask for tears	Ensure the mask is correctly orientated	Bring the mask to your nose level and place the ties over the crown of your head and secure with a bow	Using two hands, mould the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece	Then take the bottom ties, one in each hand, and secure with a bow at the nape of your neck	Pull the bottom of the mask over your mouth and chin